



GAO

Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

B-293752

March 12, 2004

The Honorable Judd Gregg
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable W.J. "Billy" Tauzin
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:
Bar Code Label Requirement for Human Drug Products and Biological
Products*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA), entitled "Bar Code Label Requirement for Human Drug Products and Biological Products" (Docket No. 2002N-0204). We received the rule on March 2, 2004. It was published in the Federal Register as a final rule on February 26, 2004. 69 Fed. Reg. 9120.

The final rule requires certain human drug and biological product labels to have bar codes that must contain the National Drug Code number in a linear bar code. FDA states that the rule will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug is being given to the right patient at the right time.

The final rule has an announced effective date of April 26, 2004. The Congressional Review Act requires a 60-day delay in the effective date of a major rule from the date of publication in the Federal Register or receipt of the rule by Congress, whichever is later. 5 U.S.C. 801 (a)(3)(A). The rule was published in the Federal Register on February 26, 2004. While the rule was received by the Senate on February 24, 2004,

the House of Representatives did not receive it until March 2, 2004. Therefore, the rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of the FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the FDA, with the exception of the delay in effective date discussed above, complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"BAR CODE LABEL REQUIREMENT FOR
HUMAN DRUG PRODUCTS AND BIOLOGICAL PRODUCTS"
(DOCKET NO. 2002N-0204)

(i) Cost-benefit analysis

FDA conducted a cost-benefit analysis using both a 7 percent and a 3 percent discount rate to arrive at the annualized costs and benefits of the final rule over 20 years.

	<u>7 Percent</u> (In Millions)	<u>3 Percent</u> (In Millions)
Regulatory Costs	\$8	\$7
Anticipated Hospital Costs	\$660	\$600
Societal Benefits	\$5,200	\$4,900
Net Benefits	\$4,500	\$4,300
Potential Hospital Efficiencies	\$380 to \$600	\$360 to \$570

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

FDA performed a Final Regulatory Flexibility Analysis and has concluded that the final rule will not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The final rule contains a private sector mandate, as defined in title II, of more than \$110 million in any one year. FDA prepared the required written statement as part of its economic impact analysis and its Final Regulatory Flexibility Analysis.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On March 14, 2003, FDA published a Notice of Proposed Rulemaking in the Federal Register. 68 Fed. Reg. 12500. In response, the FDA received approximately 190 comments, which are discussed in the preamble to the final rule.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. OMB has approved the collection and assigned OMB control number 0910-0537 with an expiration date of February 28, 2007. The total estimated annual burden is 1,777,550.5 hours.

Statutory authorization for the rule

The final rule is promulgated under the authority of sections 201(n), 201(p), 501, 502, 503, 505, and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n), 321(p), 351, 352, 353, 355, and 371(a)) and sections 351 and 361 of the Public Health Service Act (21 U.S.C. 262 and 264).

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

FDA has determined that the final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact statement.